UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA, Plaintiff, v. 512 cases, more or less, of an article of food, labeled in part: Outer Carton: "*** PART # 29673 *** Lot # 420664 *** Exp. Date 04/16 *** 12-BT Per Case – 90CT ***," Bottle: "*** USPlabs OxyELITE Pro Super Thermogenic™ *** DIETARY SUPPLEMENT 90 capsules *** Proprietary Blend *** 1,3-Dimethylamylamine HCl *** Manufactured for USPlabs, LLC (Dallas, TX 75220) ***," and 1030 cases, more or less, of an article of food, labeled in part: Outer Carton: "*** PART # 16307 Lemon-Lime Flavor *** Lot # N02090-C *** Exp. Date 04/16 6-BT Per Case – 250.00g," "*** PART # 16307 Lemon-Lime Flavor *** Lot # N02090-D *** Exp. Date 04/16 6-BT Per Case – 250.00g," "*** PART # 16307 Lemon-Lime Flavor *** Lot # N02115-A *** Exp. Date 04/16 6-BT Per Case – 250.00g,"	Case No. _____

Bottle:

"*** USPlabs Jack3d™ *** DIETARY SUPPLEMENT *** 250g *** Proprietary Blend *** 1,3-Dimethylamylamine HCl, *** Manufactured for USPlabs, LLC (Dallas, Texas 75220) ***"

and

all other articles of food labeled as containing 1,3 Dimethylamylamine HCl (DMAA) or its chemical equivalent in various flavors, sizes, and forms and various sized containers

that are located anywhere on the premises of GNC Holdings, Inc., Buncher Commerce Park, Bldg. 15A, Leetsdale, Pennsylvania, to which are affixed labels bearing, among other things, the name and address of the manufacturer identified as USPlabs, Dallas, Texas, which is located outside the Commonwealth of Pennsylvania,

Defendants.

VERIFIED COMPLAINT FOR FORFEITURE *IN REM*

The United States of America, by its attorney David J. Hickton, United States Attorney for the Western District of Pennsylvania, hereby states as follows:

NATURE OF THE ACTION

1. This Complaint is filed by the United States of America and requests seizure and condemnation of articles of food, as described in the caption, in accordance with the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. § 301 *et seq.*

JURISDICTION AND VENUE

2. This Court has jurisdiction over this *in rem* action commenced by the United States under 28 U.S.C. § 1345 and 21 U.S.C. § 334.

3. Venue is appropriate in this district pursuant to 28 U.S.C. § 1395(b) and 21 U.S.C. § 334(a)(2) because the defendant property is located in this district.

4. There is at Leetsdale, Pennsylvania, in the possession of GNC Holdings Inc., Buncher Commerce Park, Building #15A, Leetsdale, Pennsylvania, or elsewhere within the jurisdiction of this Court, articles described in the above caption that are foods within the meaning of 21 U.S.C. § 321(ff), which consist in whole or in part of ingredients that were shipped in interstate commerce from outside the Commonwealth of Pennsylvania (the "Defendant Articles").

5. This Court has *in rem* jurisdiction over the Defendant Articles because they are located in the Western District of Pennsylvania.

BASIS FOR FORFEITURE

6. The Defendant Articles are adulterated when received in interstate commerce and while held for sale, within the meaning of the Act, 21 U.S.C. § 342(a)(2)(C)(i), because they contain the food additive DMAA, which is unsafe within the meaning of 21 U.S.C. § 348.

7. By reason of the foregoing, the articles are held illegally within the jurisdiction of this Court and are liable to seizure, condemnation, and forfeiture pursuant to 21 U.S.C. § 334.

REGULATORY FRAMEWORK

8. Under 21 U.S.C. § 342(a)(2)(C)(i), a food is deemed to be adulterated if it contains any food additive that is unsafe within the meaning of Section 348 of the Act.

9. DMAA is a food additive as the term is defined under the Act. Under 21 U.S.C. § 321(s), a substance intended to become a component of food is a food additive unless: (1) it is generally recognized among experts qualified by scientific training and experience to evaluate its

safety as having been adequately shown to be safe under the conditions of its intended use; (2) it is subject to prior sanction or approval under applicable statutes; or (3) it is an ingredient described in 21 U.S.C. § 321(ff) (a dietary ingredient). Other exceptions listed in 21 U.S.C. § 321(s) are not relevant to DMAA.

10. DMAA does not satisfy the first exception because it is not generally recognized as safe under the conditions of its intended use. DMAA does not satisfy the second exception because it is not the subject of a sanction or approval pursuant to the Act, or the other applicable statutes described in 21 U.S.C. § 321(s). Finally, DMAA is not a dietary ingredient because it does not meet any of the elements of 21 U.S.C. § 321(ff)(1). DMAA is therefore a food additive.

11. DMAA is also an unsafe food additive. Under 21 U.S.C. § 348(a) of the Act, a food additive is deemed unsafe unless: (1) it is used in conformity with a regulation prescribing conditions under which it may be safely used; (2) it has been granted an exemption for investigational use under 21 U.S.C. § 348(j); or (3) it is a food contact substance. DMAA meets none of these conditions and is therefore deemed unsafe.

12. Therefore, any article of food containing DMAA is deemed to be adulterated under 21 U.S.C. § 342(a)(2)(C)(i) because it contains a food additive that is unsafe, as those terms are defined in the Act.

FACTS

13. United States Food and Drug Administration ("FDA") investigators conducted an inspection of GNC Holdings Inc.'s facility at Leetsdale, Pennsylvania from June 4, 2013 through June 10, 2013. During the inspection, the investigators identified Jack3d™ and OxyElite Pro Super Thermogenic™ as being labeled as containing 1,3-Dimethylamylamine HCl ("DMAA").

Also during the inspection, the investigators collected physical samples, photographed product containers and cases, and collected interstate shipping records. On June 11, 2013, pursuant to authority granted under 21 U.S.C. § 334(h), the FDA placed the Defendant Articles under Administrative Detention Order Number 0080, with notice provided to GNC Holdings Inc.

14. All articles of food located anywhere at GNC Holdings Inc. labeled as containing the ingredient DMAA or its chemical equivalent shipped from USPlabs in Dallas, Texas to GNC Holdings Inc., located in Leetsdale, Pennsylvania, are adulterated within the meaning of 21 U.S.C. § 342(a)(2)(C)(i).

15. By reason of the forgoing, the Defendant Articles are held illegally within the jurisdiction of this Court and are liable to seizure and condemnation pursuant to 21 U.S.C. § 334.

16. WHEREFORE, the United States prays that:

(a) a warrant of arrest issue for all the Defendant Articles as described in the caption that are located in the warehouse of GNC Holdings Inc., Leetsdale, Pennsylvania;

(b) notice be given to all parties who reasonably appear to have a potential interest in the Defendant Articles to appear and answer the allegations of the Complaint;

(c) condemnation and judgment be entered declaring that the Defendant Articles be forfeited to the United States and granting the United States the costs of this proceeding against the claimant of the articles;

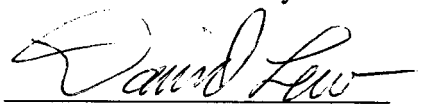
(d) the Defendant Articles be disposed of pursuant to the provisions of the Act; and

(e) the United States be granted such other and further relief that the Court deems just and proper.

Dated: June 20, 2013

Respectfully submitted,

DAVID J. HICKTON
United States Attorney



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VERIFICATION

I Lynn S. Bonner, a Compliance Officer for the United States Food and Drug Administration, U.S. Department of Health and Human Services, have read the foregoing Verified Complaint for Forfeiture In Rem and state that its contents are true and correct to the best of my knowledge, information, and belief.

I verify and declare under penalty of perjury that the foregoing is true and correct.

Executed on this 20th day of June, 2013.

Lynn S. Bonner
Compliance Officer
Food and Drug Administration
U.S. Department of Health and
Human Services